



May 8, 2003

**WARNING LETTER**

**VIA OVERNIGHT DELIVERY**

Creating Health Institute  
13300 Bothell-Everett Hwy, #6129  
Mill Creek, WA 98012

Dear sir or madam:

The Food and Drug Administration (FDA) has reviewed your web site at the following address: [www.leaf lady.org](http://www.leaf lady.org). This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your product Millenium CF. You can find the Act and implementing regulations through links on FDA's Internet home page at [www.fda.gov](http://www.fda.gov).

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. Your web site claims that your product is useful in the prevention and treatment of Severe Acute Respiratory Syndrome (SARS) and other diseases. The labeling of your product bears the following claims:

“SARS remedy” “designed to support ... your immune system against viruses” “For colds, flu, fever, ... new and emerging viruses”

These claims cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act. Because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). These drugs are also misbranded within the meaning of section 502(a) of the Act because their labeling is false and misleading in that it suggests that these drugs are effective for the prevention and treatment of SARS and other diseases, when, in fact, these claims are not supported by reliable scientific evidence. These drugs are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use.

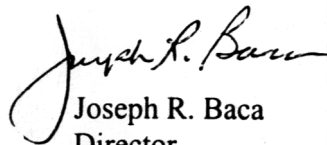
The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Compliance Officer Jennifer Thomas at the above address.

Sincerely,

A handwritten signature in black ink, reading "Joseph R. Baca". The signature is fluid and cursive, with the first letter of each word being capitalized and prominent.

Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety and  
Applied Nutrition